

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent No.: 7,488,734 Conf. No.: 7149
Issued: February 10, 2009 TC/A.U.: 1617
Appl. No.: 10/601,438 Examiner: Hui, S.
Filed: June 23, 2003
Patentee: Fensome et al
Cust. No.: 38199
Title: METHODS OF TREATING HORMONE-RELATED CONDITIONS
USING THIO-OXINDOLE DERIVATIVES

Mail Stop Patent Extension
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sirs:

STATEMENT OF FACTS
ACCOMPANYING REQUEST FOR RECONSIDERATION OF PATENT TERM
ADJUSTMENT PURSUANT TO 37 CFR § 1.705(d)

1. This Statement of Facts is respectfully submitted in support of the Application for Patent Term Adjustment Including Request for Reconsideration Under 37 CFR §1.705(d) for the above-referenced application. For the reasons set forth below, it is respectfully request that Patentees be granted a patent term adjustment of 1164 days.

2. Erroneous Calculation of Delay

The US Patent and Trademark Office failed to take into account all of the patent term adjustment (PTA) days that Patentees are entitled to pursuant to 35 CFR § 154(b)(1)(B) ("B Delay") when calculating the patent term adjustment. The PTA under 35 U.S.C. §154(b) indicated on the above-identified patent is 639 days (a copy of the

face of the patent is submitted herewith as Exhibit "A"). This determination of 639 days is in error as it only reflects a portion of the days to which Patentees are entitled.

3. Examination Delays Pursuant to 37 CFR §1.702 and §1.703

Pursuant to 35 U.S.C. §154(b), the term of patent shall be extended one day for each day that the Office failed to take certain action within the time frame specified in 35 CFR § 154(b)(1)(A) [37 CFR §1.702(a)] (hereinafter "A Delay") and failed to issue a patent within three years of the actual filing date of the above-referenced application in accordance with 35 CFR § 154(b)(1)(B) [37 CFR §1.702(b)] (hereinafter "B Delay"). In the above-referenced application, Patentees are entitled to a period of examination delay equal to the sum of the periods of delay under §1.703(a) and (b) for the following reasons.

(A) "A Delay"

Pursuant to 37 CFR §1.703(a)(1), Patentees are entitled to a period of patent term adjustment due to the failure by the Office to mail an action under 35 U.S.C. §132 not later than 14 months after the actual filing date of the application (hereinafter "14 Month Delay"). Thus, under 37 CFR §1.703(a)(1) Patentees are entitled to a PTA equal to the period between the date which is 14 months from the filing date and the date of a first Office Action on June 30, 2006 (676 days).

In addition, pursuant to 37 CFR §1.703(a)(2), Patentees are entitled to a period of patent term adjustment due to the failure by the Office to mail an action under 35 U.S.C. §132 not later than 4 months after the date of reply under 37 CFR §1.111 (hereinafter "4 Month Delay"). Thus, under 37 CFR §1.703(a)(2), Patentees are entitled to a PTA equal to the period between the date which is 4 months from Patentees' reply and the date of a mailing of an action under §132 (*i.e.*, from June 8, 2007 to August 27, 2007 or 81 days).

Pursuant to §1.704 the period of PTA will be reduced by a period equal to the period of time in which Patentees failed to engage in reasonable efforts to conclude prosecution (hereinafter "Applicant Delay"). These days include two extensions of time obtained by Patentees to respond to two separate Office Actions (*i.e.*,

from January 13, 2007 to February 7, 2007 (26 days) and from November 28, 2007 to February 27, 2008 (92 days). Thus, the total Applicant delay under §1.704 is 118 days.

The total of 639 days reflected in on the face of the above-identified patent reflects the number of days attributable to delay under §1.703(a)(1) and (2) less the number of days attributable to “Applicant Delay” under §1.704.

(B) “B Delay” Pursuant to 37 CFR §1.703(b)

35 U.S.C. §154(b) and 37 CFR §1.702(b) require issuance of a patent within 3 years after the date on which the application was filed under 35 U.S.C. §111(a), *i.e.*, by June 23, 2006. Pursuant to 37 CFR §1.702(b)(1-5) the B Delay period shall not include certain periods specifically enumerated in the rule. In relevant part, 37 CFR §1.702(b)(1) excludes delay for any time consumed by continued examination of the application under 35 U.S.C. 132(b). Thus, the B Delay period runs from the day after the date that is 3 years from the actual filing date of the application (June 24, 2006) until the day before an RCE is filed (February 26, 2008), to provide 613 days¹.

Pursuant to 37 CFR §1.702(b)(5), delay in processing of the application by the USPTO that was requested by the Patentee should also be deducted from “B Delay” days. As described above, Patentees requested extensions of time equal to 118 days of Applicant Delay.

However, these 118 days were already used to reduce Patentees “A Delay” days from 757 to 639 days. Thus, this delay has already been applied to reduce the PTA calculation. To apply these days a second time in the PTA calculation would be unfair to Patentees, as this would result in a 236 day reduction. In the event that these 118 days had been PTO delay, Patentees would only be permitted to count these days once. Therefore, Patentees submit that they are entitled to the B Delay described above without duplicative deduction of the 118 days of Applicant Delay.

(C) Total Examination Delay Pursuant to 37 CFR §1.703(f)

As set forth in 37 CFR §1.703(f), the period of examination delay based on the grounds set forth in 37 CFR §1.702 is the sum of the period of A Delay

¹ Note that only the days of B delay that do not overlap with A delay days are included in the final PTA calculation. This is further described in section C, below.

(639 days) and the B Delay (613 days), to provide a total of 1252 days, *to the extent these periods of delay are not overlapping.*

Pursuant to *Wyeth v. Dudas*², A Delay days and B Delay days overlap only when they fall on the same calendar day. In the instant case, the period of 14 Month Delay ended on June 30, 2006. The period of B Delay began on June 24, 2006. Thus, A Delay and B Delay overlap for the period of June 24, 2006 to June 30, 2006, *i.e.* for 7 days. In addition, the entire 4 Month Delay falls on the same calendar days as some of the B Delay period, *i.e.*, for 81 additional days. Therefore, the total period of PTA delay should be reduced by the period of overlap, *i.e.*, 7 days + 81 days = 88 days.

Thus, Patentees are entitled to A Delay + B Delay (to the extent they are not overlapping) = 639 days + 613 days – 88 days = 1164 days of patent term adjustment.

(D) Calculation of Correct Patent Term Adjustment Pursuant to 37 CFR §1.703(f)

As set forth in 37 CFR §1.703(f), Patentees are entitled to a period of patent term adjustment equal to the period of examination delays reduced by the period of Applicant Delay (which was included in the USPTO's calculation of A Delay). Therefore, Patentees submit that the correct patent term adjustment for the above referenced application is 1164 days.

4. This patent is not subject to a terminal disclaimer. 37 CFR §1.705(b)(2)(iii).

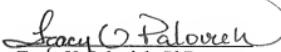
5. The only circumstances during the prosecution of the application resulting in the patent that may be considered to constitute a failure to engage in reasonable efforts to conclude processing or examination of the application as set forth in 37 CFR 1.704 are the extensions of time explained in detail in Paragraphs 3(A) and 3(B).

² *Civil Action No. 07-1492; 200 US Dist 76063 [D.D.C. September 30, 2008].*

6. In view of the foregoing, it is respectfully requested that this Application for Patent Term Adjustment be favorably considered and that a corrected Determination of Patent Term Adjustment be issued to reflect a patent term adjustment of 1164 days of the patent for the above-referenced application.

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(12) **United States Patent**
Fensome et al.

(10) **Patent No.:** US 7,488,734 B2
(45) **Date of Patent:** Feb. 10, 2009

(54) **METHODS OF TREATING HORMONE-RELATED CONDITIONS USING THIO-OXINDOLE DERIVATIVES**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 639 days.

(21) Appl. No.: 10/601,438

(22) Filed: Jun. 23, 2003

(65) **Prior Publication Data**

US 2004/0002535 A1 Jan. 1, 2004

Related U.S. Application Data

(60) Provisional application No. 60/391,826, filed on Jun. 25, 2002.

(51) **Int. Cl.**

A61K 31/505 (2006.01)

A61K 31/35 (2006.01)

(52) U.S. Cl. 514/275; 514/457; 514/336; 514/171

(58) **Field of Classification Search** 514/275, 514/457, 171, 336

See application file for complete search history.

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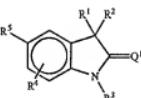
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(57)

ABSTRACT

The present invention provides methods of inducing contraception which includes delivering to a female a composition containing a compound of formula I, or tautomers thereof, in a regimen which involves delivering one or more of a selective estrogen receptor modulator, wherein formula I is:



and wherein R¹-R⁵ and Q¹ are defined as described herein. Methods of providing hormone replacement therapy and for treating carcinomas, dysfunctional bleeding, uterine leiomyomata, endometriosis, and polycystic ovary syndrome is provided which includes delivering a compound of formula I and a selective estrogen receptor modulator are also described.

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6 Claims, No Drawings